MAY - 4 2000

APPENDIX B

K000805

510(k) SUMMARY

KaVo K·E·Y Laser 1242

This 510(k) summary of safety and effectiveness for the KaVo K·E·Y Laser 1242 is submitted in accordance with the requirements of SMDA 1990 and follows guidance from the Office of Device Evaluation concerning the organization and content of a 510(k) summary.

| | |
|---|---|
| Applicant: | KaVo America Corporation<br>340 East Main Street<br>Lake Zurich, IL 60047 |
| Address (Manufacturer): | KaVo Dental GmbH<br>Bahnhofstr. 20<br>D-8847 Warthausen<br>Biberach<br>GERMANY |
| Contact Person: | Mr. John Franz, President<br>KaVo America Corporation<br>340 East Main Street<br>Lake Zurich, IL 60047 |
| Telephone: | 847-550-6800<br>847-550-6825 (Fax)<br>800-323-8029 |
| Preparation Date: | March 2000 |
| Device Trade Name: | KaVo K·E·Y Laser 1242 |
| Common Name: | Erbium:YAG surgical laser |
| Classification Name: | Surgical Laser |
| Class: | Class II |
| Legally marketed predicate devices: | SEO TriLase; Laserscope Er:YAG, Premier Centauri |

| | |
|---|---|
| Description of Device: | The KaVo K·E·Y Laser 1242 is an Er:YAG laser operating at 2.94 microns with energy output up to 500 mJ. |
| Intended Use: | The KaVo K·E·Y Laser 1242 is intended for the incision, excision, ablation, and vaporization of soft tissue in oral and maxillofacial surgery and dentistry and for the ablation and vaporization of hard tissue in dentistry. |

Performance Data: The specifications and intended uses of the KaVo K·E·Y Laser 1242 are the same or very similar to those of the claimed predicate lasers. There are no significant differences between the KaVo K·E·Y Laser 1242 and the claimed predicates in design or under conditions of intended use.

Because of this, performance data were not required.

CONCLUSION: Based on the foregoing, KaVo America Corporation believes that the KaVo K·E·Y Laser 1242 is substantially equivalent to cited legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2000

Mr. John Franz
President
KaVo America Corporation
340 East Main Street
Lake Zurich, Illinois 60047

Re: K000805
Trade Name: KaVo KEY Laser 1242
Regulatory Class: II
Product Code: GEX
Dated: March 10, 2000
Received: March 13, 2000

Dear Mr. Franz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lachman

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX A
Rev. April

# INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K000805

Device Name KaVo K·E·Y Laser 1242

Indications For Use:

The KaVo K·E·Y Laser 1242 is intended for ablation and vaporization of hard tissue in dentistry. The uses include the:

Removal of carious lesions
Enamel etching
Cavity Preparation

The KaVo K·E·Y Laser 1242 will be labeled as a prescription device in the US. This labeling will be included in manuals and other information distributed in the United States.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use____

Donna R. Lechner

(Division Sign-Off)
Division of General Restorative Devic
510(k) Number K000805